UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

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| COLOPLAST A/S,<br><br>Plaintiff,<br><br>v.<br><br>GENERIC MEDICAL DEVICES, INC.,<br><br>Defendant. | CASE NO. C10-227BHS<br><br>ORDER DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT |

This matter comes before the Court on Defendant Generic Medical Devices, Inc.'s ("Generic") motion for summary judgment (Dkt. 105). The Court has considered the pleadings filed in support of and in opposition to the motion and the remainder of the file and hereby denies the motion for the reasons stated herein.

## I. PROCEDURAL HISTORY

On February 8, 2010, Plaintiff Coloplast A/S ("Coloplast") filed a complaint for patent infringement against Generic alleging that Generic is infringing United States Patent No. 6,638,211 (the "'211 Patent") and United States Patent No. 7,621,864 (the "'864 Patent") (collectively "Patents-in-Suit"). *Id.* ¶¶ 9-17. On March 1, 2010, Generic answered and asserted numerous affirmative defenses including invalidity. Dkt. 17.

On July 21, 2011, the Court issued an order construing the disputed claims of the Patents-in-Suit. Dkt. 50.

On December 14, 2011, Generic filed a motion for summary judgment of invalidity. Dkt. 105. On January 3, 2012, Coloplast responded. Dkt. 112. On January 6, 2012, Generic replied. Dkt. 116.

## II. FACTUAL BACKGROUND

Both the '211 Patent and the '864 Patent are entitled "Method for Treating Urinary Incontinence in Women and Implantable Device Intended to Correct Urinary Incontinence." The patents also contain the same introductory paragraph that reads as follows:

> The invention relates to a method for treating urinary incontinence in women. It also relates to an implantable device intended to correct urinary incontinence in women. The said device is more particularly suited to the treatment of stress urinary incontinence.

*See, e.g.*, '211 Patent, col. 1, ll. 16-20.

Generic asserts that there are two surgical techniques for treating urinary incontinence by placing a sling under the urethra and through the obturator foramen, the "outside-in" approach and the "inside-out" approach. Dkt. 112 at 6. In an outside-in transobturator procedure, external incisions are made in the external skin in the region of the obturator foramen. Declaration of Aaron Wainscoat ("Wainscoat Decl."), Exh. I, Expert Report of Daniel Elliot, M.D. ("Elliott Report") at 36. An Emmet needle or trocar is then led through the external incision of the perineal skin (i.e. from outside the body to the inside of the body), through the obturator foramen and out through an internal vaginal incision. *Id*. The end of the sling is then attached to the trocar, or led through the eye of an Emmet needle, and then pulled back through the vaginal incision, through the muscle and obturator foramen, and out through the perineal incision. *Id*. These steps are performed with respect to each of the ends of the sling – i.e. each of the ends of the sling are retracted by the trocar or Emmet needle through a vaginal incision, along the path made by the trocar or Emmet needle and out through the incision in the perineal skin.

This is known as the "outside-in" transobturator technique, named for the path of the introducer which begins outside the patient. *Id*.

In an "inside-out" transobturator procedure, a vaginal incision is made and the sling is pre-attached to the end of a trocar that is shaped for use with the "inside-out" transobturator procedure. Then the trocar with attached sling is inserted into the vaginal incision and the sling is pushed through the tissue and the obturator foramen and exits through an external incision in the perineal skin. Elliott Report at 42. This is known as the "inside-out" technique based upon the path of the trocar which begins in the vaginal incision inside of the patient, and takes a different route through the body than a needle or trocar used in an "outside-in" approach.

During claim construction, Generic argued that the Court should add language to the claims of the Patents-in-Suit because it "is necessary to make clear that the Patents-in-Suit are limited to the 'outside-in'" procedure. Dkt. 35 at 26. The Court rejected Generic's argument and proposed construction. Dkt. 50 at 11-12. The Court concluded that adding the proposed language would violate the canon of claim construction not to import limitations from the specific embodiment disclosed in the specification into the claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005). For example, the specific embodiment disclosed in the '211 Patent describes an "outside-in" procedure wherein an Emmet needle is inserted from the outside of the body and, once the tape is placed in the eye of the needle, the needle is "pulled back" through the relevant region of the body. '211 Patent, col. 3, ll. 31–56. Claim 1 of the '211 Patent claims a method comprising the step of "extending each of the free ends of said tape in the region of two obturator foramen of the iliac wing and leading them out into the groin opposite the corresponding foramen . . . ." *Id.*, col. 4, ll. 34–37. The Court construed these terms in their ordinary and customary meanings. Dkt. 50 at 11–12.

In the instant motion, Generic requests a ruling of law on the same issue, albeit approached via different requirement for patentability.

## III. DISCUSSION

Generic moves for summary judgment that the Patents-in-Suit are invalid because (1) they do not provide an adequate written description of the claimed invention and (2) they do not enable one of ordinary skill in the art to practice the claimed invention. Dkt. 105.

### A. Summary Judgment Standard

Summary judgment is proper only if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The moving party is entitled to judgment as a matter of law when the nonmoving party fails to make a sufficient showing on an essential element of a claim in the case on which the nonmoving party has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). There is no genuine issue of fact for trial where the record, taken as a whole, could not lead a rational trier of fact to find for the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (nonmoving party must present specific, significant probative evidence, not simply "some metaphysical doubt"). *See also* Fed. R. Civ. P. 56(e). Conversely, a genuine dispute over a material fact exists if there is sufficient evidence supporting the claimed factual dispute, requiring a judge or jury to resolve the differing versions of the truth. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 253 (1986); *T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987).

The determination of the existence of a material fact is often a close question. The Court must consider the substantive evidentiary burden that the nonmoving party must meet at trial – e.g., a preponderance of the evidence in most civil cases. *Anderson*, 477

U.S. at 254; *T.W. Elec. Serv., Inc.*, 809 F.2d at 630. The Court must resolve any factual issues of controversy in favor of the nonmoving party only when the facts specifically attested by that party contradict facts specifically attested by the moving party. The nonmoving party may not merely state that it will discredit the moving party's evidence at trial, in the hopes that evidence can be developed at trial to support the claim. *T.W. Elec. Serv., Inc.*, 809 F.2d at 630 (relying on *Anderson*, 477 U.S. at 255). Conclusory, nonspecific statements in affidavits are not sufficient, and missing facts will not be presumed. *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888-89 (1990).

**B. Invalidity Standard**

Under § 282 of the Patent Act of 1952, "[a] patent shall be presumed valid" and "[t]he burden of establishing in-validity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282. The section also "requires an invalidity defense to be proved by clear and convincing evidence." *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238, 2242 (2011).

**C. Written Description**

One requirement of a valid patent is that the patent contain an adequate written description of the invention claimed. Section 112 of Title 35 provides in part as follows:

> The specification shall contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [claimed invention] . . . .

35 U.S.C. § 112; *see also Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353–54 (Fed. Cir. 2010) (en banc) ("[A] separate requirement to describe one's invention is basic to patent law. Every patent must describe an invention. It is part of the quid pro quo of a patent; one describes an invention, and, if the law's other requirements are met, one obtains a patent.").

"[T]he purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.'" *Id*. The requirement "serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based and to demonstrate that the patentee was in possession of the invention that is claimed." *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

As stated by the Federal Circuit, "[t]he test for sufficiency of a written description is whether the disclosure clearly allow[s] persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Crown Packaging Technology, Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1380 (Fed. Cir. 2011) (internal quotations omitted, alterations in original). The "hallmark of written description is disclosure," and a court examining the sufficiency of a written description must make "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad*, 598 F.3d at 1351. "The disclosure must reasonably convey[ ] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Crown*, 635 F.3d at 1380 (internal quotations omitted, alteration in original). In other words, "the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Ariad*, 598 F.3d at 1351.

The inquiry into the written description requirement is a question of fact and is "amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1361 (Fed. Cir. 2011) (quoting *PowerOasis, Inc. v. T–Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008)). To prevail, a challenger to validity must provide clear and convincing evidence that persons skilled in the art would not recognize in the

disclosure a description of the claimed invention. *Centocor Ortho Biotech, Inc. v. Abbott Laboratories*, 636 F.3d 1341, 1347 (Fed. Cir. 2011).

In this case, Generic argues that the Patents-in-Suit are invalid because the written descriptions do not disclose the "inside-out" procedure. Generic's current argument is similar to the argument it advanced during claim construction and is based on the premise that the patents only cover the disclosed specific embodiment, the "outside-in" procedure. The Court again rejects this argument, and, with respect to the current burden, the Court finds that Generic has not only failed to provide clear and convincing evidence in support of its position, but also has failed to show that no reasonable juror could find for Coloplast.

Coloplast argues that the claimed inventions relate to the transobturator procedure itself regardless of whether the tape is pushed (inside-out) or pulled (outside-in) through the patient's body. Dkt. 112 at 13-18. The Court finds that the record contains admissible evidence that a reasonable juror could return a verdict for Coloplast on this issue. First, the '211 Patent discloses a technique that is "contrary to the surgical techniques employed in the state of the art" wherein the tape was "led up alongside the bladder to form a U and thus be situated in close proximity to vital organs . . . ." '211 Patent, col. 2, ll. 19–22. Instead, in practicing the claimed invention, the tape is "diverted from the bladder to form a V" such that "no risk of damaging the bladder, the iliac artery or the small intestine is run." *Id*. at ll. 23–25. This is accomplished by "extending" and "leading" the tape from the vaginal incision out into the groin. *Id*. at 13–15. The Court finds that a reasonable juror could find that "extending" and "leading" encompasses both pushing (inside-out) or pulling (outside-in) the tape sling.

Second, Coloplast's expert has testified that a person of ordinary skill in the art would understand the claimed invention to encompass both techniques. Specifically, Dr. Elliot stated that "both the outside-in and inside-out transobturator approaches involve

'extending each of the free ends of the tape' in the region of the two obturator foramen and leading them out into the groin opposite the corresponding foramen." Elliot Report at 50. A genuine dispute over a material fact exists if there is sufficient evidence supporting the claimed factual dispute, requiring a judge or jury to resolve the differing versions of the truth. *Anderson*, 477 U.S. at 253. At the very least, Dr. Elliot's testimony is sufficient evidence supporting Coloplast's version of the factual dispute requiring a jury to resolve the issue.

Therefore, the Court denies Generic's motion for summary judgment because material questions of fact exist whether the Patents-in-Suit contain an adequate written description.

**D. Enablement**

Section 112 of Title 35 also provides that the patent specification must also describe the "the manner and process of making and using [the claimed invention]" in adequate terms to "enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [claimed invention] . . . ." 35 U.S.C. § 112. This provision is commonly known as the enablement requirement. "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *ALZA Corp. v. Andrx Pharmaceuticals, LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (quoting *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997)). "Enablement is not precluded where a 'reasonable' amount of routine experimentation is required to practice a claimed invention, however, such experimentation must not be 'undue.'" *Id*. In *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988), the Federal Circuit set forth the following factors that a court may consider when determining if a disclosure requires undue experimentation:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

858 F.2d at 737. A court need not consider all of the *Wands* factors in its analysis, but rather, a court is only required to consider those factors relevant to the facts of the case. *See Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

Whether the enablement requirement has been satisfied is a question of law based upon underlying facts, and is determined as of the patent's effective filing date. *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008).

In this case, there is at least a question of fact on the issue of enablement. For example, Dr. Elliot has asserted that one of ordinary skill could practice the full scope of the claimed invention, including the "inside-out" procedure, without undue experimentation. Elliot Report at 37–39 & 60–62.

Generic's arguments to the contrary are based on the premise that the specification must provide the "inside-out" specific embodiment in order for this procedure to be encompassed by the claim language. *See* Dkt. 116 at 3-6. This is simply not the law as there is no requirement that the specification disclose every embodiment of the claimed invention. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996) ("The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims."). With regard to Generic's burden on the instant motion, Generic has failed to provide clear and convincing evidence that one of ordinary skill in the art must engage in undue experimentation in order to practice the claimed invention by pushing the tape instead of pulling the tape. Therefore, the Court denies Generic's motion for summary judgment on the issue of enablement.

## IV. ORDER

Therefore, it is hereby

**ORDERED** that Generic's motion for summary judgment (Dkt. 105) is **DENIED**.

DATED this 6th day of February, 2012.

BENJAMIN H. SETTLE
United States District Judge